

NOT FOR INTRATHECAL USE

For retrograde pyelography
Not intended for intravascular injection

DESCRIPTION

Reno-30 is a radiopaque contrast agent for retrograde pyelography supplied as a sterile, aqueous solution. Each mL provides 300 mg diatrizoate meglumine with 3.2 mg sodium citrate as a buffer, 0.4 mg edetate disodium as a sequestering agent, and 1 mg methylparaben and 0.3 mg propylparaben as preservatives. Each mL of solution also contains approximately 141 mg organically bound iodine. At the time of manufacture, the air in the container is replaced by nitrogen.

INDICATIONS

Reno-30 is intended for retrograde or ascending pyelography. This procedure may be used if intravenous excretion urography is contraindicated and it is also useful in complementing other diagnostic information.

CONTRAINDICATIONS

Reno-30 is contraindicated for use in intrathecal procedures.

Contraindications pertain to the procedure of retrograde pyelography rather than to the administration of the medium *per se*.

Retrograde pyelography should not be performed in those conditions which do not allow for the successful catheterization of the ureters such as extensive urinary tuberculosis, tumors of the bladder, impassable obstructions of the ureters, or marked enlargement of the prostate gland.

WARNINGS

Severe Adverse Events—Inadvertent Intrathecal Administration

Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These serious adverse reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to insure that this drug product is not inadvertently administered intrathecally.

The possibility exists for inadvertent administration into the intrathecal space during epidural administrations. Therefore, epidural administration procedures, such as pain management catheter placement, should not be performed with use of this product.

General

Apart from the possible adverse effects of diatrizoate meglumine, the hazards of the performance of a retrograde genitourinary procedure exist. These include such complications as hematuria, perforation of the ureter or bladder, introduction of infection into the genitourinary tract, and oliguria or anuria.

PRECAUTIONS

Because of the possibility of inducing temporary suppression of urine, it is wise to avoid repetition of retrograde pyelography within 48 hours in patients with reduced renal function.

Retrograde pyelography should be performed with caution in patients with a known active infectious process of the urinary tract. Contrast agents may interfere with some chemical determinations made on urine specimens; therefore, urine should be collected before administration of the contrast medium or two or more days afterwards.

ADVERSE REACTIONS

The incidence of adverse reactions with diatrizoate meglumine is very low. Costovertebral angle tenderness, elevated temperature and flank pain have been reported in a few patients following use of the preparation for retrograde pyelography, as have nausea, sweating and flushing.

Irritation of the urinary tract mucosa attributable to the contrast agent itself is not likely to occur. However, the technique of retrograde pyelography may be painful and may initiate pelvic, caliceal, or ureteral spasms with consequent renal colic.

Since retrograde pyelography does not involve systemic administration of a contrast agent, the risk of severe reactions, which may occur with intravenous administration, is extremely remote. However, they should be kept in mind whenever a contrast agent is administered. Severe reactions may be manifested by edema of the face and glottis, respiratory distress, convulsions, or shock; such reactions may prove fatal unless promptly controlled by such emergency measures as maintenance of a clear airway and immediate use of oxygen and resuscitative drugs. Like other sensitivity phenomena, severe reactions are more likely to occur in patients with a personal or family history of bronchial asthma, significant allergies, drug reactions, or previous reactions to contrast agents.

DOSAGE AND ADMINISTRATION

Preparation of the patient: Appropriate preparation is desirable for optimal results. A laxative the night before the examination and a low residue diet the day before the procedure are recommended.

Dosage: The usual dose for patients aged 16 years or more is 15 mL for unilateral and appropriately increased volumes for bilateral pyelograms. Approximately 5 to 6 mL will generally be required for each exposure. The dosage for children should be proportionately smaller than the adult dose.

As supplied, the preparation provides maximum opacification. If a lesser contrast is desired, it may be diluted with sterile distilled water.

Administration: Reno-30 may be introduced by a gravity flow system or by syringe. When the syringe method is used, the injections should be made slowly and care should be exercised to use as little manual pressure as possible. Regardless of the system used, injection of the contrast medium should be terminated as soon as the patient complains of a sense of fullness or pain in the renal region.

Radiography: The commonly employed radiographic techniques should be used. A scout film is recommended before the contrast agent is administered.

HOW SUPPLIED

Reno-30 (Diatrizoate Meglumine Injection USP 30%) is available in packages of: Twenty-five 50 mL multiple dose vials (NDC 0270-0804-45).

Storage

The preparation should be protected from strong light and stored at 20–25°C (68–77°F) [See USP]; avoid freezing.

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